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(पहला पुनरीक्षण)

Indian Standard

HAZARD ANALYSIS AND CRITICAL CONTROL
POINT (HACCP) — REQUIREMENTS FOR ANY
ORGANIZATION IN THE FOOD CHAIN
(*First Revision*)

ICS 67.020

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FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Food Hygiene, Safety Management and Other Systems Sectional Committee had been approved by the Food and Agriculture Division Council.

The HACCP system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. Any HACCP system is capable of accommodating change, such as, advances in equipment design, processing procedures or technological developments.

HACCP can be applied throughout the food chain from the primary producer to final consumer and its implementation should be guided by scientific evidence of risks to human health. Besides enhancing food safety, implementation of HACCP can provide other significant benefits. The application of HACCP system can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.

Successful application of HACCP requires full commitment and involvement of the management and the workforce. It also requires a multi-disciplinary approach; this multi-disciplinary approach should include, where appropriate, expertise in agronomy, veterinary health, production microbiology, medicine, public health, food technology, environmental health, chemistry, and engineering according to the particular study. The application of HACCP is compatible with the implementation of quality management systems, such as, the IS/ISO 9000 series and IS/ISO 22000 and is a system of choice in the management of food safety within such systems. While the application of HACCP to food safety has been considered here, the concept can be applied to other aspects of food quality.

Keeping in view the above, this standard was first published in 1998 based on the Guidelines for the Application of the Hazard Analysis and Critical Control Point (HACCP) System (CAC/GL 18-1993) published by the Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, Rome and was identical to it. Codex later included the guidelines as Annex to the third revision of Recommended International Code of Practice — General Principles of Food Hygiene [CAC/RCP-1(1969), Rev. 3 (1997)]. The fourth revision of Recommended International Code of Practice — General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4- 2003) has necessitated the first revision of this standard, wherein the text has been updated and aligned with the Annex of CAC/RCP 1-1969, Rev. 4- 2003. In this revision guidelines for small and/or less developed businesses which do not have the resources and the necessary expertise on site for the development of HACCP plan have been included to facilitate implementation of an effective HACCP plan by them. Further, record keeping system has been elaborated with additional examples.

Nothing in this standard shall affect the operation of the *Food Safety and Standards Act, 2006* and regulations framed thereunder; *Standards of Weights and Measures Act, 1977* or any other law for the time being in force and shall be subject to the restrictions imposed thereunder, wherever applicable.

Indian Standard

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) — REQUIREMENTS FOR ANY ORGANIZATION IN THE FOOD CHAIN

(*First Revision*)

1 SCOPE

This standard sets out the principles of the hazard analysis and critical control point (HACCP) system and provides general guidelines for the application of these principles, while recognizing that the details of application may vary depending on the circumstances of the food operation.

2 REFERENCES

The standard listed below contains provision which through reference in this text, constitutes provision of this standard. At the time of publication, the edition indicated was valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below:

<i>IS No.</i>	<i>Title</i>
2491 : 2013	Food hygiene — General principles — Code of practice (<i>third revision</i>)

3 DEFINITIONS

For the purpose of this standard, the following definitions shall apply.

3.1 Control (Verb) — To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

3.2 Control (Noun) — The state wherein correct procedures are being followed and criteria are being met.

3.3 Control Measure — Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

3.4 Corrective Action — Any action to be taken when the results of monitoring at the CCP indicate a loss of control.

3.5 Critical Control Point (CCP) — A step at which control can be applied and is essential to prevent or

eliminate a food safety hazard or reduce it to an acceptable level.

3.6 Critical Limit — A criterion which separates acceptability from unacceptability.

3.7 Deviation — Failure to meet a critical limit.

3.8 Flow Diagram — A systematic representation of the sequence of steps of operations used in the production or manufacture of a particular food item.

3.9 HACCP — A system which identifies, evaluates and controls hazards which are significant for food safety.

3.10 HACCP Plan — A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

3.11 Hazard — A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

3.12 Hazard Analysis — The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore, should be addressed in the HACCP plan.

3.13 Monitor — The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

3.14 Step — A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

3.15 Validation — Obtaining evidence that the elements of the HACCP plan are effective.

3.16 Verification — The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

4 PRINCIPLES

The HACCP system consists of the following seven principles:

- a) *Principle 1* — Conduct a hazard analysis.
- b) *Principle 2* — Determine the critical control points (CCPs).
- c) *Principle 3* — Establish critical limit(s).
- d) *Principle 4* — Establish a system to monitor control of the CCP.
- e) *Principle 5* — Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
- f) *Principle 6* — Establish procedures for verification to confirm that the HACCP system is working effectively.
- g) *Principle 7* — Establish documentation concerning all procedures and records appropriate to these principles and their application.

5 GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

5.1 Prior to application of HACCP to any sector of the food chain, that sector should be operating according to IS 2491, the appropriate Indian Standards/Codes of Practice, and appropriate food safety legislation (*Food Safety and Standards Act*, 2006 and regulations framed thereunder). These pre-requisite programs to HACCP, including training, should be well established, fully operational and verified in order to facilitate the successful application and implementation of the HACCP system.

5.2 For all types of food business, management awareness and commitment is necessary for implementation of an effective HACCP system. The effectiveness shall also rely upon management and employees having the appropriate HACCP knowledge and skills. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP system, consideration should be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

5.3 The intent of the HACCP system is to focus control at CCPs. Re-design of the operation should be considered, if a hazard which must be controlled is identified but no CCPs are found.

5.4 HACCP should be applied to each specific operation separately. CCPs identified in any given example in any Indian Standard on Code of hygienic

practice, or elsewhere, might not be the only ones identified for a specific application or might be of a different nature.

5.5 HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step.

5.6 The application of the HACCP principles should be the responsibility of each individual businesses. However, there may be obstacles that hinder the effective application of the HACCP principles by individual business. This is particularly relevant in small and/or less developed businesses. While it is recognized that when applying HACCP, flexibility appropriate to the business is important, all seven principles must be applied in the HACCP system. This flexibility should take into account the nature and size of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints.

5.7 Small and/or less developed businesses do not always have the resources and the necessary expertise on site for the development and implementation of an effective HACCP plan. In such situations, expert advice should be obtained from other sources, which may include: trade and industry associations, independent experts and regulatory authorities. HACCP literature and especially sector-specific HACCP guides can be valuable. HACCP guidance developed by experts relevant to the process or type of operation may provide a useful tool for businesses in designing and implementing the HACCP plan. Where businesses are using expertly developed HACCP guidance, it is essential that it is specific to the foods and/or processes under consideration.

5.8 The efficacy of any HACCP system will nevertheless rely on management and employees having the appropriate HACCP knowledge and skills, therefore, ongoing training is necessary for all levels of employees and managers, as appropriate.

6 APPLICATION OF HACCP PRINCIPLES

6.0 Application of HACCP principles consists of the following tasks as identified in the logical sequence for application of HACCP (*see Fig. 1*).

6.1 Assemble HACCP Team

6.1.1 The food operation should assure that the appropriate product specific knowledge and expertise is available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on site, expert advice should be obtained from other sources, such as, trade and

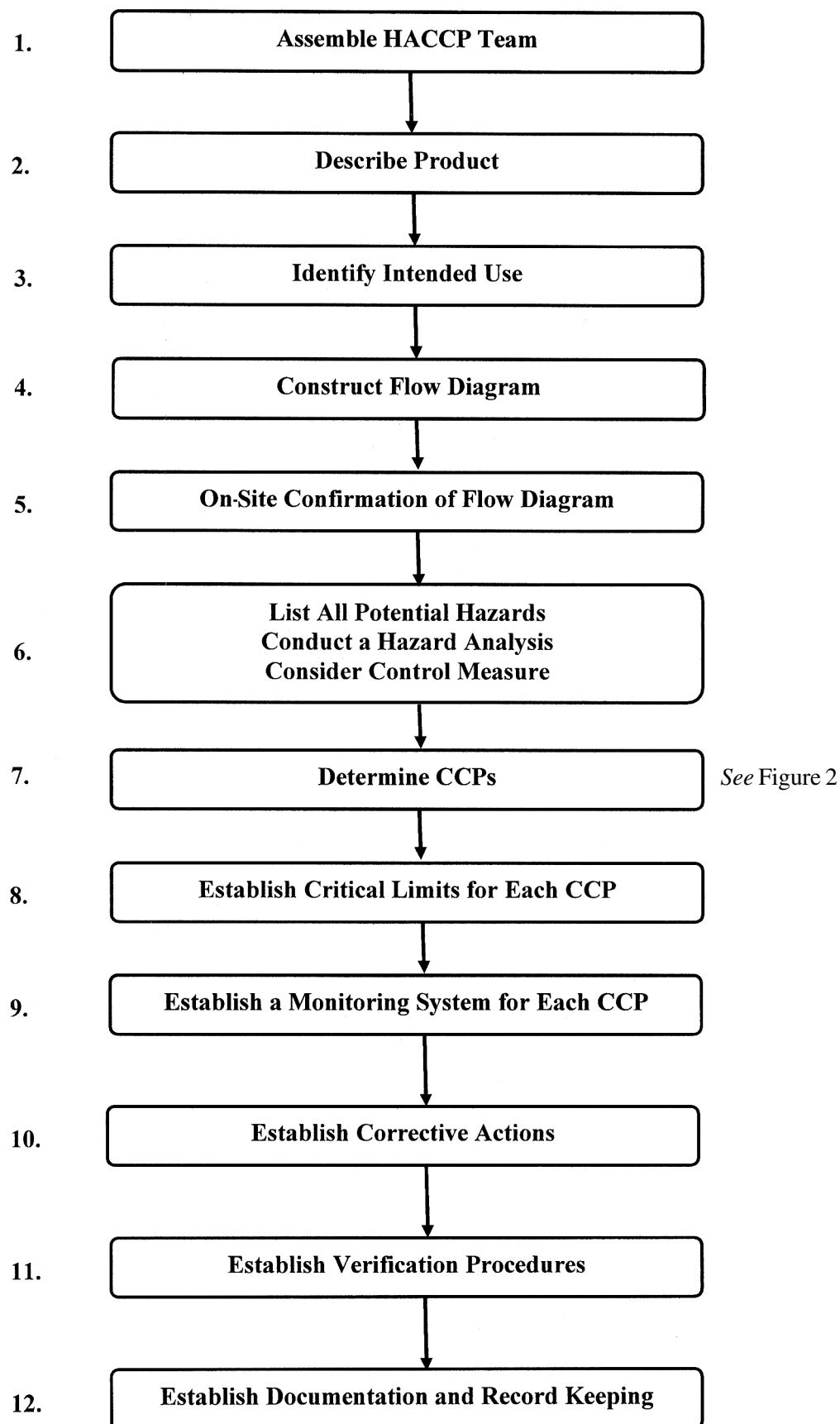


FIG. 1 LOGICAL SEQUENCE FOR APPLICATION OF HACCP

industry associations, independent experts, regulatory authorities, HACCP literature and HACCP guidance (including sector-specific HACCP guides). It may be possible that a well-trained individual with access to such guidance is able to implement HACCP in-house.

6.1.2 The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed (for example, Does it cover all classes of hazards or only selected classes?).

6.2 Describe Product

A full description of the product should be drawn up, including relevant safety information, such as, composition, physical/chemical structure [including water activity (*Aw*), *pH*, etc], microcidal/static treatments (for example, heat-treatment, freezing, brining, smoking, etc), packaging, durability and storage conditions and method of distribution. Within businesses with multiple products, for example, catering operations, it may be effective to group products with similar characteristics or processing steps, for the purpose of development of the HACCP plan.

6.3 Identify Intended Use

The intended use should be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, such as, institutional feeding, may have to be considered.

6.4 Construct Flow Diagram

The flow diagram should be constructed by the HACCP team (*see* 6.1.1). The flow diagram should cover all steps in the operation. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specific operation. The confirmation of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation.

6.5 On-Site Confirmation of Flow Diagram

The HACCP team should confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. The confirmation of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation.

6.6 Conduct a Hazard Analysis [See 4(a)]

6.6.1 The HACCP team should list all the hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture and distribution till the point of consumption.

6.6.2 The HACCP team should next conduct a hazard

analysis to identify for the HACCP plan, hazards which are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.

6.6.3 In conducting the hazard analysis, wherever possible, the following should be included:

- a) The likely occurrence of hazards and severity of their adverse health effects;
- b) The qualitative and/or quantitative evaluation of the presence of hazards;
- c) Survival or multiplication of micro-organisms of concern;
- d) Production or persistence in foods of toxins, chemicals or physical agents; and
- e) Conditions leading to the above.

6.6.4 The HACCP team should then consider what control measures, if any, exist which can be applied for each hazard.

6.6.5 More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

6.7 Determine Critical Control Points (CCPs) [See 4(b)]

6.7.1 There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree (*see* Fig. 2), which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. It should be used for guidance when determining CCPs. This example of a decision tree may not be applicable to all situations. Other approaches may be used. Training in the application of the decision tree is recommended.

6.7.2 If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

6.8 Establish Critical Limits for Each CCP [See 4(c)]

6.8.1 Critical limits should be specified and validated if possible for each critical control point. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, *pH*, *Aw*, and available chlorine, and sensory parameters, such as, visual appearance and texture.

6.8.2 Where HACCP guidance developed by experts

(answer questions in sequence)

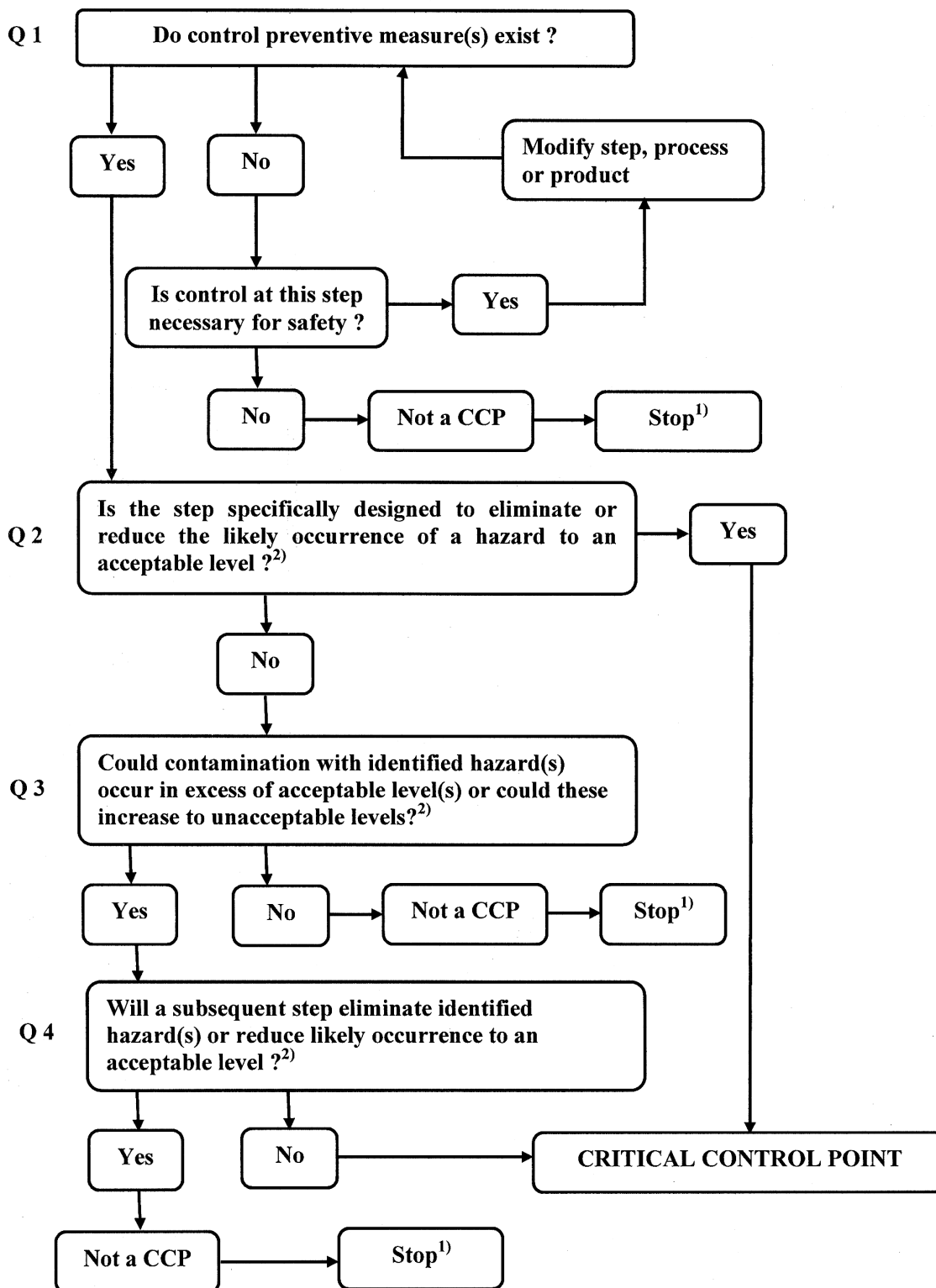
¹⁾ Proceed to the next identified hazard in the described process.²⁾ Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCPs of HACCP plan.

FIG. 2 EXAMPLE OF DECISION TREE TO IDENTIFY CCPs

has been used to establish the critical limits, care should be taken to ensure that these limits fully apply to the specific operation, product or groups of products under consideration. These critical limits should be measurable.

6.9 Establish a Monitoring System for Each CCP [See 4(d)]

6.9.1 Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits.

6.9.2 The monitoring procedures should be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits.

6.9.3 Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs.

6.9.4 Data derived from monitoring should be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.

6.9.5 If monitoring is not continuous, then the amount or frequency of monitoring should be sufficient to guarantee that the CCP is in control.

6.9.6 Most monitoring procedures for CCPs will need to be done rapidly because they relate to on line processes and there will not be time for lengthy analytical testing.

6.9.7 Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product.

6.9.8 All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

6.10 Establish Corrective Actions [See 4(e)]

6.10.1 Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur.

6.10.2 The actions must ensure that the CCP has been brought under control. Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping.

6.11 Establish Verification Procedures [See 4(f)]

6.11.1 Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be

used to determine if the HACCP system is working correctly.

6.11.2 Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties.

6.11.3 The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. Examples of verification activities include:

- a) review of the HACCP system and its records;
- b) review of deviations and product dispositions; and
- c) confirmation that CCPs are kept under control.

6.11.4 Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP plan.

6.12 Establish Documentation and Record Keeping [See 4(g)]

6.12.1 Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained. Expertly developed HACCP guidance materials (for example, sector-specific HACCP guides) may be utilized as part of the documentation, provided that those materials reflect the specific food operations of the business.

6.12.1.1 Documentation examples are:

- a) Hazard analysis,
- b) CCP determination, and
- c) Critical limit determination.

6.12.1.2 Record examples are:

- a) CCP monitoring activities,
- b) Deviations and associated corrective actions,
- c) Verification procedures performed, and
- d) Modifications to the HACCP system.

6.12.2 An example of a HACCP worksheet is given in Fig. 3 for guidance.

6.12.3 A simple record-keeping system can be effective and easily communicated to employees. It may be integrated into existing operations and may use existing paperwork, such as, delivery invoices and checklists to record, for example, product temperatures.

Describe Product

Diagram Process Flow

LIST							
Step	Hazard(s)	Control Measure(s)	CCPs	Critical Limit(s)	Monitoring Procedure(s)	Corrective Action(s)	Record(s)

Verification

FIG. 3 EXAMPLE OF A HACCP WORKSHEET

7 TRAINING

7.1 Training of personnel in industry, government and academia in HACCP principles and applications, and increasing awareness of consumers are essential elements for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions and procedures should be developed which define the tasks of the operating

personnel to be stationed at each critical control point.

7.2 Co-operation between primary producer, industry, trade groups, consumer organizations and responsible authorities is of vital importance. Opportunities should be provided for the joint training of industry and control authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards : Monthly Additions'.

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